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Informed Consent in California

Latent Liability Without 'Negligence'

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Informed consent is a legal obligation due from a physician to his patient, an obligation which may not be met by the physician's skillful treatment of his patient. It may only be met by the treating physician obtaining from his patient knowing authorization for carrying out the intended medical procedure. The physician is required to disclose whatever would be material to his patient's decision, including the nature and purpose of the procedure, and the risks and alternatives. The disclosures should be made by the physician to his patient, and not through use of consent forms which are not particular to individual patients. To minimize any subsequent claim by the patient that there was a lack of adequate disclosures, the physician should record in the patient's chart the circumstances of the patient's consent, and should not rely on the patient's unreliable ability to recall those circumstances.

THE CONCEPT of informed consent emerged in the early 1900's from legal cases involving circumstances where no consent had been given for the medical procedure done. The most extreme example was a situation in which a patient consented to a medical procedure which was erroneously carried out on another patient, who had never given his consent to any procedure. A more common example was where a patient consented to a particular medical procedure and some other procedure was done. Liability was founded in these cases not on negligent treatment, but on the unconsented-to touching of the patient. The patient never consented to any medical procedure, and yet carrying out any medical procedure necessarily involves touching the patient. The touching, being unconsented-to, was in civil law technically a "battery." No matter how skillfully the unconsented-to medical procedure was done, there was still liability for the unconsented-to and, therefore, wrongful touching or battery. The concept of informed consent was premised on the basic principle that every competent adult has the right to determine what shall be done with his own body. (This principle was first enunciated in 1914

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by Justice Benjamin Cardozo, in *Schloendorff v. Society of New York Hospital,* 211 N.Y. 125, 105 N.E. 92 [1914]). Accordingly, no medical procedure may be done on a competent adult without his consent. The concept has two basic elements: first, that the patient is entitled to information on the proposed treatment and, second, that based on that information the patient must consent to the treatment before it may properly be carried out.*

The significance of the lack of informed consent, as measured by the frequency with which it gives rise to malpractice actions, is not clear. There is some feeling that the lack of consent is asserted in a large number of medical malpractice actions because it potentially offers a patient recovery even where there has been no negligence in treatment. In 1973 the Department of Health, Education, and Welfare (DHEW) published an extensive report on medical malpractice, including statistics concerning informed consent.[1] As set forth in that report, since 1961 the concept has become more significant as an issue in malpractice cases. DHEW found that informed consent was an issue in 6.6 percent of all medical malpractice appellate court decisions in the United States during the period 1961 through 1971 and was the most significant issue in 4.7 percent of those same appellate court decisions.

Whatever the significance of the concept may have been nationwide, it received dramatic new impetus in California in 1972 in a landmark decision by the California Supreme Court in *Cobbs vs Grant* (8 Cal. 3d 229; 104 Cal. Rptr. 505, 502 P. 2d 1 [1972]). The patient in that case, Cobbs, had a duodenal ulcer and consent was obtained from him for a vagotomy. When his consent was obtained, he was not informed of the risks of a vagotomy, including the risk of a possible injury to his spleen and possible subsequent development of a gastric ulcer. Both of these things occurred, resulting in a subsequent splenectomy and then a gastrectomy. Cobbs sued his surgeon, Grant. He claimed that Grant had carried out the vagotomy negligently and, alternatively, even if he had not negligently done the vagotomy, he was otherwise liable because no valid consent had been obtained, the consent having been given without disclosure of the risks of a vagotomy. The jury returned a verdict for Cobbs without specifying whether it was based on negligence in doing the vagotomy or on the lack of informed consent. Grant appealed the decision and the Supreme Court reversed it, finding no substantial evidence of negligence and sending the case back to the trial court to determine whether there was informed consent. The Court in remanding the case reviewed the standards applicable to an informed consent and in so doing made significant new law.

The Court first clarified that while carrying out a medical procedure without any consent constitutes a battery, doing it without informed consent constitutes negligence.

The Court then determined that in obtaining an informed consent the adequacy of a doctor's disclosure to his patient is subject to a legal standard and not a medical standard. (Before *Cobbs,* there was a split of authority in California on the applicable standard, most courts holding that a medical standard applied requiring a doctor to disclose only such information as would be disclosed by a doctor in good standing within the medical community [*Cobbs, supra,* 8 Cal. 3d at 241]). According to the Court, a doctor is required to disclose all information relevant to a meaningful decision by the patient, generally including the nature of the proposed procedure, its purpose, the risks involved, and the alternatives to performing the procedure.† The Court stated:

> In sum, the patient's right of self decision is the measure of the physician's duty to reveal. That right can be effectively exercised only if the patient possesses adequate information to enable an intelligent choice. The scope of the physician's communications to the patient, then, must be measured by the patient's need, and that need is whatever information is material to the decision. Thus the test for determining whether a potential peril must be divulged is its materiality to the patient's decision. (8 Cal. 3d at 245.)

The Court recognized that the scope of disclosure defied simple definition and found that there were at least two applicable limitations. First, no long discourse was necessary about all the possible complications which might occur. The Court felt that a patient was principally concerned with those complications involving risk of serious injury or death and those relating to re-

*A general review and analysis of informed consent was prepared for the American Medical Association Office of the General Counsel and appeared in a series of law and medicine notes in JAMA as follows: Holder AR: Informed consent—Its evolution. JAMA 214:1181-1182, Nov 9 1970; Holder AR: Informed consent—The obligation. JAMA 214:1383-1384, Nov 16, 1970; Holder AR: Informed consent—Limitations. JAMA 214:1611-1612, Nov 23, 1970; Simonaitis JE: Recent decisions on informed consent. JAMA 221:441-442, Jul 24, 1972; Simonaitis JE.: More about informed consent: Part 1. JAMA 224:1831-1832, Jun 25, 1973; Simonaitis JE: More about informed consent: Part 2. JAMA 225:95-96, Jul 2, 1973.

†For mnemonic purposes, disclosure requirements may best be remembered by equating *"nature, purpose, risks* and *alternatives"* with *"no* physician *risks* the *alternatives"* of failing to provide such disclosure.

cuperation. Second, the Court stated that there need not be disclosure of slight risks from common procedures. As an example of a common procedure, the Court referred to the drawing of a blood sample, the risks of which include, among others, septicemia, endocarditis, thrombophlebitis, pulmonary embolism and death. However, not withstanding the seriousness of any of these risks, they are infrequent occurrences, and given the common nature of the procedure involved—that is, drawing blood—none of the foregoing risks need be disclosed.

Even where disclosure is required and none has been given, liability will not automatically attach for the failure to make the necessary disclosure. The Court held that even in these circumstances there is no liability unless it is established that, had the disclosure been made, consent to the proposed procedure would not have been given. The Court stated the patient has the right to testify that had disclosure been made he would not have consented to the procedure. But the Court recognized that a patient who has gone through a stormy recovery or possibly suffered permanent disability may not be completely free from prejudice. Accordingly, the Court determined that the test of liability will depend not upon the patient's analysis of whether he would have consented but upon whether a prudent person in the patient's position, when fully informed, would have consented to the procedure. If such a prudent person when fully informed would have consented, then no liability attaches. If such a prudent person when fully informed would not have consented, then liability will attach.

Even where no disclosures are made, the Court determined there were two defenses to liability. First, if the patient requests that no disclosure be made, then none is required and no liability will attach for not having provided the disclosure. Second, if the disclosure would prevent the patient from dispassionately weighing the risks, then no disclosure is required. But as to this latter defense the Court stated the doctor will have to show by a preponderance of the evidence that that was the case. (Notwithstanding the Court's comments, this second defense should never be applicable. Meaningful consent requires full disclosure. If a patient is not competent to receive all the information then he is not competent to give a valid consent. In such circumstances, the consent should be obtained from those who may be legally qualified to consent on his behalf.)

The *Cobbs* decision emphasizes the importance of informed consent in California. The patient must be informed of whatever would be material to his decision, which generally includes the nature of the procedure, its purpose, the risks and the alternatives. It is the patient who has the right to determine whether to have the recommended procedure done. Only the patient, and not his treating doctor, is in a position to evaluate the patient's nonmedical needs, whatever they may be, and to determine on the basis of those needs what should be done to his own body. (The recent trend of informed consent cases emphasizing the patient's rights as exemplified in *Cobbs* has been both praised as vesting the ultimate determination of treatment where it properly belongs—with the patient,[2] and damned as creating a legalistic fiction that destroys good patient care.[3])*

While *Cobbs* is a landmark decision setting forth significant new law, there has been no study quantitating how widely known it is among the California medical community and, if known, what effect if any it has had on procedures for obtaining informed consent. In June 1974 the California Medical Association published a special report on informed consent, in the form of questions and answers, reviewing the major holdings of *Cobbs*.[4] In addition, various committees of the California Medical Association have published position papers for anesthesiologists, family practitioners, neurologists, ophthamologists, orthopedic surgeons, pathologists, pediatricians, urologists, physicians specializing in chest diseases, and physicians specializing in physical medicine and rehabilitation.†

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*For a further analysis of *Cobbs* see Bamberg DF: Informed consent after Cobbs—Has the patient been forgotten? San Diego Law Rev 10:913-927, Jun 1973; Novack BB: Informed consent and the patient's right to "no." Loyola of Los Angeles Law Rev 6:384-397, Jul 1973; Kassenick LW, Mankin PA: Medical malpractice: The right to be informed. Univ. San Francisco Law Rev. 8:261-281, Winter 1973.

†See the following pamphlets: *On the Matter of Informed Consent for the California Anesthesiologist,* California Society of Anesthesiologists and the Scientific Advisory Panel to the Section on Anesthesiology, California Medical Association (CMA); *Informed Consent in Chest Diseases,* CMA Scientific Advisory Panel to the Section on Chest Diseases; *Informed Consent,* Committee Report, CMA Section on General and Family Practice; *On the Subject of Informed Consent for Neurological Procedures,* CMA Scientific Advisory Panel to the Section on Neurology; *Suggested Guidelines for Ophthalmologists re Informed Consent,* CMA Scientific Advisory Panel to the Section on Ophthalmology; *On the Matter of Informed Consent for California Orthopaedic Surgeons,* CMA Scientific Advisory Panel to the Section on Orthopedics; *Informed Consent in Pathology,* CMA Scientific Advisory Panel to the Section on Pathology; *Some Thoughts on Informed Consent in Pediatrics,* CMA Scientific Advisory Panel to the Section on Pediatrics; *Informed Consent in the Specialty of Physical Medicine & Rehabilitation,* CMA Scientific Advisory Panel to the Section on Physical Medicine and Rehabilitaton; and *Informed Consent in Urology,* CMA Scientific Advisory Panel to the Section on Urology. (California Medical Association Scientific Advisory Panels, 731 Market Street, San Francisco, CA 94103.)

There is no question that *Cobbs* has resulted in some changes in obtaining informed consent, which perhaps are best exemplified by changes in consent forms. While it is unknown to what extent consent forms have changed, in some circumstances they have changed from a "blank check" form in which the patient authorizes the doctor to perform a particular procedure and anything else the doctor deems necessary, to a form in which the patient is informed that he has a right to be told of the nature and purpose of the proposed procedure, the risks of complications and the alternative procedures which may be available. (A good example of this latter form is the new model consent form for teaching hospitals prepared by the California Hospital Association, which in relevant part provides as follows: "Doctor _____ has explained to me that these surgical operations and special diagnostic and therapeutic procedures all may involve calculated risks of complications, injury or even death, from both known and unknown causes, and no warranty or guarantee has been made as to result or cure. I recognize that I have a right to be informed of the nature and purpose of the operation or procedures, the risks of complications, and the alternative methods of treatment, if applicable. Further, I recognize that this form is not intended to be a substitute for the explanations of the nature and purpose of the operation or procedures, the risks of complications, and the alternative methods of treatment, if applicable, which are to be provided by the physician mentioned above . . . ."[5])

Under *Cobbs* the adequacy of consent procedures may be analyzed by considering the appropriate use and limitations of consent forms. Consent forms should not be relied upon to provide the disclosures required by *Cobbs*. The problem with consent forms is that they are not particular to an individual patient. While the nature and even the purpose of a particular procedure may be fairly general from patient to patient, the risks and alternatives of a particular procedure will vary from patient to patient depending on the patient's age, his health and the acuteness of his medical problem. Where the nature and the purpose of a particular procedure do not change from patient to patient, then they may adequately be disclosed in a consent form, but generally a particular procedure's risks and alternatives should never be disclosed by use of consent forms. Rather they should be disclosed orally by the treating physician to his patient. An example of this dichotomy is a consent form for an angiogram in which the nature of an angiogram is set forth and then the patient is informed of the estimated complication rates for carotid, brachial and femoral studies; informed of the rates for permanent complications and mortality, and is provided with an overall grave complication rate of permanent paralysis or death. While the statistics on complications may be completely valid and interesting to the medical profession, they are averages and are not particular to an individual patient; they therefore may be misleading as to the risks to the patient whose informed consent is sought.

Although consent forms should not be relied upon to meet the disclosures required by *Cobbs,* they may serve a valuable function if they are used to ensure that those disclosures are made by the treating physician to his patient, that the patient understands those disclosures and that the patient understands that it is solely his discretionary decision as to whether the recommended procedure will be carried out. If consent forms are to serve the function of ensuring informed consent within the meaning of *Cobbs,* they should contain the following provisions: First, "Your consent to any medical procedure is an important decision, as any medical procedure may involve the risks of serious injury or death from known or unknown causes and for which no guarantee may be made." This provision informs the patient that any procedure which will require his consent is serious in nature and must be carefully considered because of the consequences which may occur, and that as to any medical procedure there may be no guarantees of results.* Second, "You have a right to be informed by your doctor of the nature and purpose of the procedure to be performed, the possible complications, and any alternative methods of treatment which may be available, all of which your doctor will explain to you in terms you can understand." This term informs the patient of what he is entitled to know, tends to ensure that he will be provided with all the disclosures required by *Cobbs,* and tends to reduce the likelihood of the patient claiming that he was not so informed. Third, "You are en-

*In one California appellate decision subsequent to *Cobbs,* a patient was informed that the contemplated procedure involved the risk of serious injury or death, but the nature of the possible serious injury was not disclosed. The Court determined in that instance that the disclosure given, while not specifying the type of risks involved, was nonetheless sufficient under *Cobbs. Morgenroth vs Pacific Medical Center, Inc.,* 54 Cal. App. 3d 521, 126 Cal. Rptr. 681, (1st Dist. 1976).

couraged to ask questions about what your doctor tells you." This clause helps insure that the patient will understand what he has been told. Fourth, "Do not sign this consent form unless from what your doctor explains, you have an understanding of what procedure is to be done, the purpose of the procedure, the possible complications, and what alternative procedures may be available, and unless considering your understanding you desire your doctor to perform the procedure." This statement is a further explanation of provisions two and three above, and emphasizes that it is the patient who has the right to determine whether or not the proposed procedure is to be carried out. Fifth, "Even after giving your consent by signing this form, you are free at any time, prior to the performance of the procedure to withdraw your consent." This statement reemphasizes that it is the patient's right to determine whether to have the procedure performed and that that right is a continuing right.

Regardless of whether a consent form is employed, the treating physician should be mindful that there will always be some question as to whether the disclosures were in understandable terms. Under *Cobbs,* it is incumbent upon the treating physician to ensure that the disclosures have been stated in terms understandable to a competent lay person. If the treating physician is to minimize the possibility of any subsequent claim by his patient that there was either a lack of disclosure, or lack of understandable disclosure, then the treating physician's record of his authorization to proceed should not consist solely of his patient's signed consent. Rather in obtaining any consent, the treating physician should record in the patient's chart the disclosures made, and the fact that the patient was given an opportunity to ask questions concerning those disclosures, that the patient acknowledged his understanding of the disclosures, and that in the physician's opinion the patient when consenting was competent to and did understand those disclosures.

The importance of recording the foregoing information in the patient's chart cannot be overemphasized. Following any medical procedure, a patient may not remember what he was informed, whether he had any understanding of what he was told and—if suit is brought—he may well testify that he was never provided with any disclosures. There has been little research done on what a patient remembers of the circumstances of his consent, but there has been at least one reported study.

Drs. George Robinson and Avraham Merav recorded all informed consent conversations with their cardiac surgical patients at Montefiore Hospital and Medical Center in New York for a period beginning in January 1975.[6] The patients were given *Cobbs* type disclosures. Four to six months after operation, 20 patients were randomly selected for repeat interviews to determine their recall of what they had been informed before giving their consent. The patients were graded on a scale from 0 to 100 percent for primary recall (their recall without any suggestion of what they had been informed), and 0 to 100 percent on their secondary recall (what they could remember with suggestion of what they had been told). The findings were reported at the Twelfth Annual Meeting of the Society for Thoracic Surgeons in January 1976.

Drs. Robinson and Merav found that there was poor retention in all categories of disclosure. The poorest retention was on potential complications, for which there was 10 percent primary recall and 23 percent secondary recall. In other words, the 20 patients reinterviewed on the average could remember only 10 percent of what they were told about potential complications, without suggestion of what they had been told. They could remember only 23 percent of what they had been told about potential complications, with suggestion of what had been said. For the 20 patients for all categories of information, 17 scored 50 percent or less on primary recall, and 12 scored 50 percent or less on secondary recall. The patients' average recall of information was 29 percent primary recall, and 42 percent secondary recall. Sixteen of the 20 patients denied that certain major items of disclosure were discussed at all, and 13 of these 16 denied having been informed on multiple significant items of information. Moreover, Drs. Robinson and Merav found that beyond the failure to recall, or even a denial that certain information had been conveyed, there was also in 13 of the 20 patients a significant degree of fabrication of information which supposedly had been conveyed, but which had never been conveyed. The obvious conclusion is that a doctor should not rely on his patient's memory as to informed consent.

In summary, the concept of informed consent is of increasing significance in California. The

concept involves a legal obligation imposed on a treating physician in obtaining his patient's consent, to disclose to the patient whatever information would be material to the patient's decision, including the nature and purpose of the procedure, and the risks and alternatives to the procedure. The disclosures should be made orally by the physician to his patient, and not through the use of consent forms which are not particular to individual patients. Consent forms may be of significant value if employed to inform the patient of his right to disclosures, thereby helping to ensure that the disclosures will be made and that the patient will not contend otherwise. To further ensure that the obligation has been met, and to further minimize the possibility of any subsequent contention that it was not met, the treating physician should record in the patient's chart the circumstances of the patient's consent, and should not rely on the patient's unreliable ability to recall those circumstances. Any failure by the treating physician to make the necessary disclosures exposes him to liability to his patient even though he was not negligent in the treatment of the patient.

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SKIN CANCER SURVEY

A one-year survey of nonmelanotic skin cancer in the United States is being undertaken by the National Cancer Institute and the United States Environmental Protection Agency in seven areas of the country. The survey will cover the areas of Atlanta, Detroit, New Orleans and Seattle, the San Francisco Bay area and the entire states of New Mexico and Utah. The survey has the approval of the American Academy of Dermatology.

There is growing concern regarding the possible increase in skin cancer as a result of the depletion of the ozone layer by supersonic aircraft and the use of aerosols. Increased ultraviolet radiation at the ground, apart from its effects on human beings, may affect plant and other animal life in ways that are only beginning to be understood.

Similar data on skin cancer were obtained in 1971-72 by the National Cancer Institute as part of the Third National Cancer Survey. The data have been very useful in relating the incidence of nonmelanotic skin cancer to varying degrees of ultraviolet exposure. The present survey will cover the period June 1977 through May 1978.

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